

REMARKS

Claims 1-18 are pending in the subject application. In the Non-Final Office Action of July 22, 2008, claims 1-18 stand rejected. Claim 15 has been amended to recite, "rinsing the device in the container with a rinse solution; retaining a portion of a liquid substance in the container, wherein the liquid substance comprises at least a portion of the rinse solution"; and finds support throughout the specification, such as page 3, paragraph 3. New claims 19-20 have been added and find support throughout the specification, such as page 3, paragraph 4. Claim 16 has been canceled. Applicant submits that no new matter has been introduced by way of amendment or addition of the new claims. Presently, claims 1-15 and 17-20 are pending.

A. Rejection of Claims 1, 3-9 under 35 U.S.C. §103(a)

Claims 1 and 3-9 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over U.S. Patent No. 5,961,921 to Addy et al. (hereinafter "Addy") in view of U.S. Patent No. 5,653,045 to Ferrel (hereinafter, "Ferrel"). Applicant traverses this rejection for at least the reasons set forth herein.

To determine the obviousness of a claim, an Examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Furthermore, as set forth in MPEP §2142, the key to supporting any rejection under 35 U.S.C. § 103(a) is the clear articulation of the reason why the

claimed invention would have been obvious. As the Supreme Court recently stated, “*there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

For example, where the Examiner contends that the claimed invention is obvious because of the elements gleaned from the combined teachings of Addy and Ferrel, the Examiner must explain why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Applicant respectfully submits, however, that the Examiner has failed to clearly articulate the reasoning in support of the asserted conclusion of obviousness in view of the combined teachings of Addy and Ferrel and that there is no reason why one of ordinary skill in the art would arrive at the method for cleaning and sterilizing a medical device recited in claim 1 and the claims that depend therefrom.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See MPEP §2141.02(VI). In fact, it has been held that an important indicator of non-obvious is “teaching away” from the claimed invention by the prior art or known by those of ordinary skill. See *U.S. v. Adams*, 383 US 39, 148 USPQ 479 (1966). Indeed, express teaching away from the claimed invention is a *per se* demonstration of lack of *prima facie* obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987).

Claim 1 recites, "a method for cleaning and sterilizing a medical device comprising: placing the device into a container; cleaning the device in the container with a cleaning solution; rinsing the device in the container with a rinse solution; vaporizing a liquid substance in the container to create a sterilant vapor; and contacting the device with the vapor to effect sterilization of the device."

Addy discloses a method for cleaning and sterilizing a medical device comprising: placing the device into a container; treating the device in the container with a liquid substance comprising a hydrogen peroxide, wherein a predetermined amount of the liquid substance is retained in the container and vaporized to create a sterilant vapor; and contacting the device with the vapor to effect sterilization of the device (Office Action, page 2, last paragraph to page 3, first paragraph). However, as acknowledged by the Examiner, Addy does not teach cleaning the device in the container with a cleaning solution and rinsing the device in the container with a rinse solution, as recited in claim 1. Applicant further submits that Addy does not disclose using a rinse solution comprising a chemical sterilant, such as hydrogen peroxide, as recited in claims 4 and 5.

However, the Examiner asserts that Ferrel cures the deficiencies of Addy. Ferrel discloses a method for cleaning and decontaminating wafer devices or medical devices comprising cleaning the device with a cleaning solution and rinse solution. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to clean the device in the container of Addy with a cleaning solution and rinse solution disclosed in Ferrel. Applicant respectfully disagrees. Ferrel teaches a method for cleaning and decontaminating wafer or medical devices wherein:

[f]irst, a hot sulfuric acid/hydrogen peroxide wash is used to remove organic contamination. The hot sulfuric acid/hydrogen peroxide wash is followed by an ammonium hydroxide/hydrogen peroxide rinse to remove non-metallic particles, and then a hydrochloric acid/hydrogen peroxide rinse to remove any metallic particles introduced by the high pH of the ammonium hydroxide/hydrogen peroxide rinse (col. 3, lines 45-54).

The three rinse solutions of Ferrel: hot sulfuric acid/hydrogen peroxide; ammonium hydroxide/hydrogen peroxide; and hydrochloric acid/hydrogen peroxide are used in liquid form to clean wafers or medical devices. Applicant submits that one of ordinary skill in the art would not be inclined to combine the teachings of Addy and Ferrel to arrive at the claimed invention because the cleaning process of Ferrel includes a final hydrochloric acid rinse that results in hydrochloric acid remaining in the chamber following cleaning and rinsing of the medical device. One of ordinary skill in the art would understand that vaporizing the remaining hydrochloric acid in the container could create a potentially hazardous situation.

In this regard, it has been held that "if a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed." See *In re Fritch*, 972 F.2d at 1265, 23 USPQ.2d at 1783. Furthermore, MPEP §2143.01 (VI) states "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

It is submitted that it would be improper to combine the Addy and Ferrel references because the combination or modification would destroy the intended function

and/or change the principle function of Addy, which is to provide a non-hazardous method of sterilization (col. 8, lines 42-55). The dangers of hydrochloric acid are well documented by various state and federal health departments. For example, the North Carolina Department of Health and Human Services, which employs the standards of the Occupational Safety and Health Administration (OSHA) states,

[h]ydrochloric acid should be protected from extreme temperature changes...hydrochloric acid is considered a strong oxidizer and steps should be taken to separate hydrochloric acid from incompatible materials, such as copper, brass, bronze, galvanized steel, tin, zinc, oxidizers combustible materials, plastics, rubber, and some coatings ...contact with metals causes erosion and the formation of flammable hydrogen gas. The heat generated from exothermic reaction of metal and hydrogen chloride or hydrochloric acid could cause ignition of combustible materials (See www.epi.state.nc.us/epi/oii/hcl).

Applicant submits that cleaning medical devices with liquid hydrochloric acid solutions, as taught by Ferrel, would not be particularly troublesome. However, because various medical devices are composed of materials "incompatible" with hydrochloric acid, vaporizing hydrochloric acid or any remnants of the cleaning solutions described in Ferrel in the presence of these incompatible materials would create a potentially hazardous situation, one that Addy explicitly tries to avoid.

An objective of Addy is to provide a cleaning and sterilizing method that is beneficial because of its non-hazardous nature. Addy states,

[t]he present invention provides several advantages over earlier vapor sterilization systems, such as...
(4) no toxic residues remain. The method, therefore, provides for a highly efficient, nonhazardous, and relatively inexpensive method of sterilization (col. 8, lines 42-55).

Thus, one of ordinary skill in the art, reading Addy and Ferrel, would not be directed to the method for cleaning and sterilizing a medical device as described in claim 1 and the claims that depend therefrom.

In addition, as stated in the MPEP §2143.02, “a reasonable expectation of success is required to support a *prima facie* case of obviousness.” *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). Applicant contends that one of ordinary skill in the art would not have a reasonable expectation of success of creating the claimed method of cleaning and sterilizing a medical device by combining Addy’s method of sterilization with the cleaning and rinse solutions of Ferrel. As discussed above, the cleaning and rinse solutions of Ferrell would leave remnants of hydrochloric acid that would become vaporized. One of ordinary skill in the art would recognize that vaporizing hydrochloric acid in the presence of potentially incompatible materials used in medical devices would create a potentially hazardous situation. Thus, there is no incentive to make the wholesale modifications to Addy’s method of sterilization, as suggested by the Examiner, such that a potentially hazardous method of sterilization will be the end result.

For the reasons set forth herein, the combined teachings of Addy and Ferrel do not establish a *prima facie* case for obviousness. Accordingly, Applicant respectfully requests withdrawal of the rejection to claims 1 and 3-9 under 35 U.S.C. §103(a) in view of Addy and Ferrel.

B. Rejection of Claim 2 under 35 U.S.C. §103(a)

Previous claim 2 was rejected under 35 U.S.C. §103(a) for assertedly being unpatentable over Addy in view of Ferrel further in view of U.S. Patent No. 5,711,921 to Langford et al. (hereinafter "Langford"). Applicant traverses this rejection for at least the reasons set forth herein.

As discussed in *Section A*, herein, the combination of Addy in view of Ferrel is clearly distinguished from claim 1 and the claims that depend therefrom (*i.e.* claim 2). Furthermore, Langford when combined with Addy and Ferrel provides no teaching that would render obvious claim 2. Indeed, the Examiner only cites Langford for the teaching of a method comprising storing a device in a container in sterile form.

Accordingly, Applicant respectfully requests the withdrawal of the rejection of claim 2 under 35 U.S.C. §103(a) in view of Addy and Ferrel further in view of Langford.

C. Rejection of Claims 10-14 under 35 U.S.C. §103(a)

Claims 10-14 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Addy in view of Ferrel. Applicant traverses this rejection for at least the reasons set forth herein.

Claim 10 recites, "[a] method for cleaning and sterilizing a medical device comprising: placing the device into a container; cleaning the device in the container with a cleaning solution; rinsing the device in the container with a rinse solution; retaining a predetermined amount of a liquid substance in the container; vaporizing the liquid substance in the container to create a vapor; and contacting the device with the vapor to effect sterilization of the device."

The combination of Addy and Ferrel is clearly distinguished from claim 10 and the claims that depend therefrom (*i.e.* claims 11-14) for at least the reasons set forth in *Section A*. Thus, Applicant respectfully requests the withdrawal of the rejection of claims 10-14 under 35 U.S.C. §103(a) in view of the combination of Addy and Ferrel.

D. Rejection of Claims 15 and 17-18 under 35 U.S.C. §103(a)

Previous claims 15 and 17-18 were rejected under 35 U.S.C. §103(a) for assertedly being unpatentable over Addy in view of Ferrel. Applicant traverses this rejection for at least the reasons set forth herein.

Amended claim 15 recites, “[a] method for cleaning and sterilizing a medical device comprising: placing the device into a container; cleaning the device in the container with a cleaning solution; rinsing the device in the container with a rinse solution; retaining a portion of a liquid substance in the container, wherein the liquid substance comprises at least a portion of the rinse solution; vaporizing a liquid substance in the container to create a sterilant vapor; and contacting the device with the vapor to effect sterilization of the device.”

The combination of Addy and Ferrel is clearly distinguished from claim 15 and the claims that depend therefrom (*i.e.* claims 17-18) for the reasons set forth in *Section A*. Thus, Applicant respectfully requests the withdrawal of the rejection of claims 15 and 17-18 under 35 U.S.C. §103(a) in view of the combination of Addy and Ferrel.

E. Nonstatutory Double Patenting Rejections

Claims 1-18 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/024,118. For at least the reasons set forth herein it is believed that the claims are clearly distinguished from the cited reference.

Furthermore, it is respectfully requested that the various nonstatutory double patenting issues be stayed until a final disposition of the claims has been made with respect to the section 103(a) rejections addressed above. Thereafter, the nonstatutory double patenting issues, specifically the issue of whether it is necessary to file a terminal disclaimer, can be addressed in view of the otherwise allowable subject matter and its relation to the subject matter claimed in U.S. application No. 11/024,118.

F. New Claims 19-20

Applicant respectfully submits that new claims 19-20 recite a novel and non-obvious method for cleaning and sterilizing a medical device. None of the cited references, either alone or in combination, teaches or suggests the recited method for cleaning and sterilizing a medical device for at least the reasons set forth in *Section A*.

Thus, Applicant believes that new claims 19-20 are patentable in view of the cited prior art. Accordingly, consideration and allowance of new claims 19-20 are respectfully requested.

G. Status of Related Applications

Related U.S. Patent Application No. 11/024,118 is under final rejection. An Advisory Action was mailed on September 19, 2008. In response, Applicant filed a Request for Continued Examination on October 8, 2008.

CONCLUSION

Applicant respectfully submits that claims 1-15 and 17-20 recite novel and non-obvious methods for cleaning and sterilizing a medical device. Applicant believes that these claims define over the prior art of record and are in proper form for allowance. In view of the foregoing, Applicant respectfully submits that the subject application is in condition for allowance. Accordingly, reconsideration of the rejections to claims 1-15 and 17-20 at an early date are earnestly solicited.

Applicant does not otherwise concede, however, the correctness of the rejections with respect to any of the dependent claims not discussed above. Accordingly, Applicant hereby reserves the right to make additional arguments as may be necessary to further distinguish the dependent claims from the cited references based on additional features contained in the dependent claims that were not discussed above. A detailed discussion of these differences is believed to be unnecessary at this time in view of the differences in the claims pointed out above.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below. Applicant submits that if any additional fee is necessary for consideration of this Response, the

Commissioner is hereby authorized to charge the additional required fees to Account
No. 11-1110.

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Date

Respectfully submitted,



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